


























Structured Product Labeling (SPL) OTC Sub-team Teleconference
March 14, 2011, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Amy Deuchler, Medline Industries, Inc.
-  Iris Feliciano, Tris Pharma
-  Lisa Fields, Blistex, Inc.
-  Chris Guay, Procter & Gamble
-  Michele Hewitt, Sandoz, Inc., Broomfield
-  Maureen Kapustynski, Cadbury
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team leader)
-  Kathryn Moreng, Bayer Consumer HealthCare
-  Kathy Olgers, Perrigo Company
-  Jeff Poisson, i4i
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Gary Saner, Reed Technologies and Information Services, Inc.
-  Dave Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratory, Inc.
-  Lonnie Smith, U.S. FDA Data Standards
-  Beth Thompson, Medline Industries, Inc.
-  Ranga Velagaleti, BASF Corporation
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Vu, FDA CDER
-  Ann Marie Waller, Oraceutical, LLC
-  Robert Wirt, Allergan
-  Marcia Howard, CHPA staff (sub-team liaison)

- II. Next Standing Teleconference:** **April 11, 2011, 1:00pm ET** (unless cancelled).
Standing calls for 2011 will be held on the second Monday of each month only and will be cancelled as appropriate.

III. Discussion

A. ER/DL Sub-team Call – March 30, 2011 (1:00 – 2:30 pm ET)

- FDA staff from Drug Registration and Listing System (DRLS), CBER, CVM, Compliance/Imports, and Data Standards will be participating on the call.
- Questions and scenarios have been submitted to the FDA staff in advance of the call based on industry feedback.
- All are invited to participate. Dial-in info:
 - Phone 866-213-2145
 - Access Code: 273 8216
 - Contact Pat Cowall-Hanover (COWALL-HANOVER.PATRICIA.L@LILLY.COM) for additional information

B. Inactive Ingredients in OTC Drug Listings

- FDA may conduct a manual validation review of SPL drug listing files for OTC products and if there seem to be discrepancies about the inactive ingredients listed on the label image compared to the data element section, the agency will contact the company for clarification. FDA is *not* requiring inactive ingredients be listed but is *requesting* the data be provided.
- If a company decides not to include all of the inactives in the data elements field (for which there are UNIs), it must inform FDA of the decision via email and request a manual override (a separate request, providing including the core ID of the file, must be made for each submission requiring the manual override). FDA will document its discussion with the firm about any concerns but will enter the drug listing submission into the agency database.

IV. SPL Educational Forums/Information (*For Your Information*)

- A. FDA Training Sessions: Please visit the Data Standards Council website for details about upcoming agency training opportunities.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 240184

Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.

SPL Working Group Wikipage: <http://spl-work-group.wikispaces.com/Drug+Listing> (no log-on or password needed).

- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)

Please email sub-team co-leaders Patricia Cowall- Hanover (COWALL-HANOVER PATRICIA L@LILLY.COM) or Jessica Dunn Skorupski if you want to get the email information (JSkorups@its.jnj.com).

- D. **SPL Generics Sub-team calls:** Not currently holding regular calls.
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

- E. **Medical Products Sub-team calls:** Every other Thursday at 10:30 am EST
Please email Sub-team leader Myron Finseth (myron.finseth@medtronic.com) if you want to join this sub-team.

Telephone Number: 770-657-9270
Participant passcode: 745896

- F. **SPL Usage Discussion Group**
Please email or call Terry Brunone (Theresa.M.Brunone@gsk.com; +1-215-751-3210) or Gary Saner (gsaner@reedtech.com; +1-610-731-7192) if you wish to join the discussion group.

- G. **Homeopathic Sub-team** (*new sub-team; not replacing SPL OTC sub-team*)
Initial call to be held **March 24, 2011, 1:00 – 2:00 pm ET.**

Contact sub-team leader Travis Borchardt (tborchardt@enzy.com) if you wish to join this sub-team.